Early Recoil After Balloon Angioplasty of Erection-Related Arteries in Patients With Arteriogenic Erectile Dysfunction

Diehm, Nicolas ; Do, Dai-Do ; Keo, Hak-Hong ; Boerlin, Jana ; Regli, Christian ; Schumacher, Martin ; Jungmann, Pia M ; Raeber, Lorenz ; Baumann, Frederic

Abstract: PURPOSE To evaluate the incidence of elastic recoil in patients presenting with erectile dysfunction (ED) undergoing endovascular revascularization of the pudendal or penile arteries. METHODS A consecutive series of 21 ED patients (mean age 58.3±9.3 years) undergoing minimally invasive revascularization of 31 arteries was analyzed. ED lesions included the pudendal arteries (n=27) and the penile artery (n=4). Mean lesion length was 20.6±13.9 mm. Minimal lumen diameter (MLD) measurements were assessed at baseline, immediately after balloon angioplasty, and 10 minutes thereafter. Early recoil was defined as an MLD reduction >10%. Elastic recoil with >10% lumen compromise was treated with drug-coated balloons, while severe elastic recoil (>30%) required drug-eluting stents (DES). The International Index of Erectile Function (IIEF-15) score was obtained prior to and 3 months after the procedure to obtain information on functional outcomes subsequent to angioplasty. RESULTS Mean MLD at baseline was 0.9±0.6 mm, which improved to 2.0±0.9 mm immediately after balloon dilation. At 10 minutes after dilation, the MLD was 1.7±1.0 mm. Elastic recoil was observed in all 31 lesions and resulted in a mean lumen compromise of 21.2%. Severe (>30%) recoil was observed in 14 arteries, which underwent DES therapy. The IIEF-15 score improved from 31.3±11.2 at baseline to 49.8±16.8 ($p<0.001$) at the 3-month follow-up. CONCLUSION Endovascular revascularization constitutes a safe and feasible treatment modality to restore erectile function in patients with arteriogenic ED and ineffective conservative management. Early elastic recoil is very frequent subsequent to balloon dilation of small-caliber erection-related arteries. Thus, mechanical scaffolding with DES is required in a high subset of ED patients to provide favorable early angiographic and clinical results.

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Nicolas Diehm, MD[1], Dai-Do Do, MD[1], Hak-Hong Keo, MD[1], Jana Boerlin, RN[1], Christian Regli, MD[1], Martin Schumacher, MD[2], Pia M. Jungmann, MD[3], Lorenz Raeber, MD[4], and Frederic Baumann, MD[5]

Abstract

Purpose: To evaluate the incidence of elastic recoil in patients presenting with erectile dysfunction (ED) undergoing endovascular revascularization of the pudendal or penile arteries. **Methods:** A consecutive series of 21 ED patients (mean age 58.3±9.3 years) undergoing minimally invasive revascularization of 31 arteries was analyzed. ED lesions included the pudendal arteries (n=27) and the penile artery (n=4). Mean lesion length was 20.6±13.9 mm. Minimal lumen diameter (MLD) measurements were assessed at baseline, immediately after balloon angioplasty, and 10 minutes thereafter. Early recoil was defined as an MLD reduction >10%. Elastic recoil with >10% lumen compromise was treated with drug-coated balloons, while severe elastic recoil (>30%) required drug-eluting stents (DES). The International Index of Erectile Function (IIEF-15) score was obtained prior to and 3 months after the procedure to obtain information on functional outcomes subsequent to angioplasty. **Results:** Mean MLD at baseline was 0.9±0.6 mm, which improved to 2.0±0.9 mm immediately after balloon dilation. At 10 minutes after dilation, the MLD was 1.7±1.0 mm. Elastic recoil was observed in all 31 lesions and resulted in a mean lumen compromise of 21.2%. Severe (>30%) recoil was observed in 14 arteries, which underwent DES therapy. The IIEF-15 score improved from 31.3±11.2 at baseline to 49.8±16.8 ($p<0.001$) at the 3-month follow-up. **Conclusion:** Endovascular revascularization constitutes a safe and feasible treatment modality to restore erectile function in patients with arteriogenic ED and ineffective conservative management. Early elastic recoil is very frequent subsequent to balloon dilation of small-caliber erection-related arteries. Thus, mechanical scaffolding with DES is required in a high subset of ED patients to provide favorable early angiographic and clinical results.

Keywords

atherosclerosis, elastic recoil, drug-coated balloon, drug-eluting stent, endovascular revascularization, erectile dysfunction, penile artery, pudendal arteries

Introduction

Erectile dysfunction (ED) constitutes an increasing health problem in the aging male population.[1] The prevalence of ED is age-dependent, affecting up to 86% of men >80 years. A total of 150 million men are affected worldwide.[2,3] ED may be indicative of other underlying cardiovascular diseases and thus is mostly associated with traditional cardiovascular risk factors.[4]

Arterial insufficiency is the leading cause of ED and may result from obstructions of the common and internal iliac arteries as well as the pudendal and penile arteries.[5] It was recently shown that the pudendal artery is the single most frequent arterial segment to be affected by atherosclerotic obstructions in patients with ED of arterial origin.[6] In that study, the average pudendal arterial diameter was very comparable to the average coronary artery diameter. In patients with ED attributed to arterial disease, endovascular therapy constitutes promising results to restore blood flow and improve clinical outcomes.[5,7,8] However, the ideal

[1]Vascular Institute Central Switzerland, Aarau, Switzerland
[2]Department of Urology, Hirslanden Hospital Aarau, Switzerland
[3]Department of Neuroradiology, University Hospital of Zurich and University of Zurich, Switzerland
[4]Department of Cardiology, University Hospital of Bern, Switzerland
[5]Clinic for Angiology, University Hospital of Zurich and University of Zurich, Switzerland

Corresponding Author:
Nicolas Diehm, Vascular Institute Central Switzerland, Aarenaustrasse 2B, Aarau, AG 5000, Switzerland.
Email: nicolas.a.diehm@gmail.com

antirestenotic regimen within this challenging arterial segment remains to be determined.[7]

Given that ED with arterial obstructions of oftentimes small-caliber erection-related arteries may be present even in comparatively young patients, a "leave nothing behind strategy" with drug-coated balloon (DCB) angioplasty may be a favorable treatment option. On the other hand, mechanical scaffolding with stents is regarded as necessary in other small-caliber arteries (eg, coronary or tibial).[9,10] Thus, prior to a clinical investigation aimed at finding the ideal antirestenotic therapy in pudendal artery obstructions, an assessment of early elastic recoil, an important contributor to restenosis in coronary or tibial arteries,[9,10] is warranted.

The purpose of the present study was to analyze the prevalence of elastic recoil subsequent to balloon angioplasty in ED patients undergoing endovascular therapy. This information may provide further guidance on optimizing endovascular treatment strategies in ED patients.

Methods

Study Design and Baseline Examination

This was a prospective investigation of 21 consecutive ED patients (mean age 58.3±9.3 years) unresponsive to phosphodiesterase-5 (PDE-5) inhibitor who had endovascular revascularization between March and August 2017. All patients underwent hormonal examination to exclude hypothalamic-pituitary and/or gonadal disorder, as well as thyroid dysfunction. Duplex ultrasound examination was performed in all patients to rule out venous leakage, defined as an end-diastolic velocity >0.15 m/s indicating a dysfunction of the veno-occlusive mechanism.[7] Arterial diagnostics included duplex ultrasound subsequent to the intracavernosal administration of 10 mg of prostaglandin E1 (alprostadil). In case of pathological arterial flow on penile duplex ultrasound (peak systolic velocity <0.3 m/s),[11] computed tomography angiography (CTA) of the iliac and pudendal arteries was performed to document arteriogenic ED (lumen compromise >50%) prior to endovascular revascularization. The assessed cardiovascular risk factors were defined as outlined elsewhere.[12] The International Index of Erectile Function[13] (IIEF-15) score was obtained from all patients at baseline and during follow-up at 3 months.

Ethics committee approval for the present study was waived since the procedures conformed to the standard of care in our center following earlier experiences with small-vessel angioplasty.[9]

Angiographic Imaging and Measurements

Single plane digital subtracted angiograms captured on an Artis Q system (Siemens, Erlangen, Germany) were analyzed on a PACS workstation (Siemens) by an interventional angiologist with 9 years of endovascular experience (N.D.). A stenosis was defined as a lumen compromise ⩾50%. Lesion length was measured as the distance of ⩾50% lumen compromise for stenoses or as the distance over an occlusion to the point of where the artery reconstituted. Reference vessel diameters (RVD) and minimal lumen diameters (MLD) were measured using an automated edge detection system (Siemens). MLD was assessed at baseline, immediately subsequent to angioplasty, and 10 minutes thereafter. Elastic recoil was defined as lumen compromise >10% and calculated as: [1 – (lumen gain at 15 minutes / lumen gain after dilation)] × 100.[9] Accordingly, severe elastic recoil was defined as a lumen compromise >30% 10 minutes after dilation.

Endovascular Revascularization

All procedures were performed under local anesthesia with retrograde puncture of the contralateral common femoral artery. After insertion of a 6-F sheath (Terumo Destination, Terumo, Japan), the common iliac artery was catheterized by crossover access to obtain angiographic imaging of the iliac arteries using a single-curve RIM catheter. Heparin (5000 units) was administered in all patients. Thereafter, the hypogastric and pudendal arteries were engaged under roadmap guidance with a 0.014-inch guidewire. Nitroglycerine was injected selectively into the target artery over the RIM catheter and over the 6-F sheath at the origin of the internal pudendal artery for selective/superselective angiography. Lesions of erection-related arteries were angiographically imaged in different projections and quantitatively analyzed. After crossing the lesion with a 0.014-inch guidewire (Figure 1), balloon dilation was performed with a standardized inflation time of 1 minute at nominal inflation pressure. Balloon diameters were chosen based on artery diameter measurements.

Angiography was repeated 10 minutes after the end of dilation. If elastic recoil >10% but ⩽30% was detected, DCB angioplasty was performed using Sequent Please paclitaxel-coated balloons (B. Braun, Berlin, Germany). The RVD to DCB diameter ratio was 1.01. If recoil at 10 minutes after dilation was >30%, a DES was implanted (Coroflex ISAR; B. Braun). Care was taken not to oversize the diameter of the DCB or DES beyond 10% of the RVD. In patients with multiple lesions, all lesions were consistently treated with either DCB or DES.

After endovascular therapy, all patients received dual antiplatelet therapy for 12 months (aspirin 100 mg/d plus clopidogrel 75 mg/d). In addition, tadalafil 5 mg daily was prescribed for 3 weeks subsequent to the intervention.

Patient Population

Stenotic lesions were identified in 31 arteries (27 pudendal arteries, 3 dorsal penile arteries, and 1 common penile artery). Four of the 21 patients presented with elevated end-diastolic velocities (>0.15 m/s) on duplex ultrasound, indicating

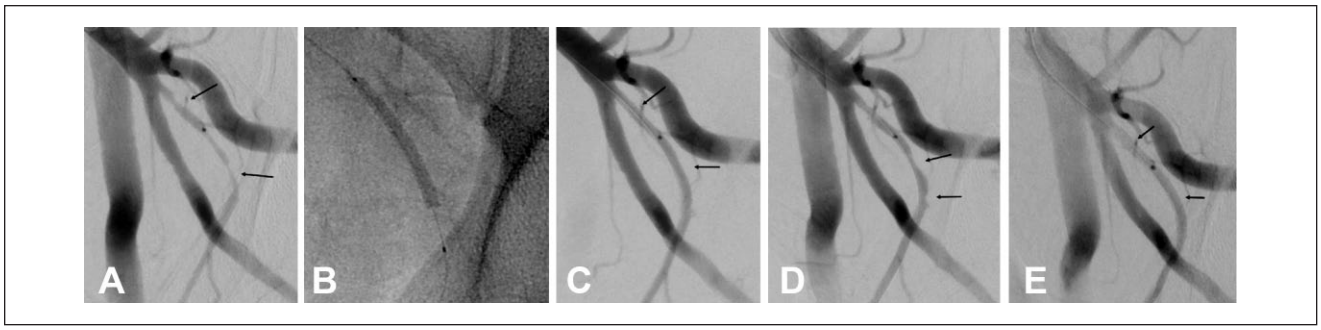

Figure 1. (A) Multifocal stenosis of the proximal left pudendal artery (arrows) in a patient with erectile dysfunction. (B) Plain balloon angioplasty using a 3×40-mm balloon after the lesion had been crossed with a 0.014-inch guidewire. (C) Immediate angiographic results after plain balloon angioplasty showing the absence of residual arterial obstruction (arrows). (D) Early elastic recoil at 10 minutes after plain balloon angioplasty (arrows). (E) Angiographic result after implantation of two 4×39-mm drug-eluting stents.

Table 1. Characteristics of 21 Patients Undergoing Endovascular Revascularization for Erectile Dysfunction Stratified by Treatment With Drug-Eluting Stent (DES) vs Drug-Coated Balloon (DCB).[a]

	Total (n=21)	DES (n=11)	DCB (n=10)	p
Age, y	58.3±9.3	57.7±8.0	59.1±11.5	0.732
Hyperlipidemia	8	5	3	0.466
Arterial hypertension	10	5	5	0.835
Diabetes mellitus	4	2	2	0.916
Coronary heart disease	4	2	2	0.916
Cerebrovascular disease	0	0	0	—
Peripheral artery disease	0	0	0	—
Smoking	14	8	6	0.537
Current	9	6	3	0.256
Former	5	2	3	0.525
Kidney disease	1	0	1	0.283
Dialysis	0	0	0	—
Alcohol abuse	2	1	1	0.943

[a]Continuous data are presented as the mean ± standard deviation; categorical data are given as the number.

concomitant venous occlusive disease. Patient characteristics are provided in Table 1 and angiographic findings in Table 2. Mean lesion length was 20.6±13.9 mm. Lesions involving the penile arteries were shorter compared with the pudendal artery lesions (4.0 vs 23.0 mm).

Clinical Outcomes

The primary endpoint was elastic recoil after balloon angioplasty; secondary endpoints included target lesion (TLR) and target vessel revascularization (TVR). In addition, the course of symptoms was assessed by administering the IIEF-15 questionnaire at baseline and 3 months after endovascular therapy; scores on 2 specific questions were compared: Question 3 [When you attempted intercourse, how often were you able to penetrate (enter) your partner?] and Question 4 [During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?].

The primary safety endpoints were puncture site complications and major adverse events at 30 days, defined as device- or procedure-related death, perineal gangrene or necrosis (glans penis, penile shaft, scrotal, or anal), or the need for subsequent perineal, penile, or anal surgery (including TLR, TVR, or arterial embolization).

Statistical Analysis

Continuous variables were expressed as means ± standard deviation. Differences were compared using an independent *t* test for parametric and the Wilcoxon rank sum test for nonparameteric variables. Categorical variables were reported as the numbers and compared using the chi-squared test. A $p<0.05$ was considered to indicate statistically significant differences. Statistical analysis was performed using STATA software (version 14.0; StataCorp, College Station, TX, USA).

Table 2. Angiographic Findings of the 31 Treated Lesions in 21 Erectile Dysfunction Patients Undergoing Endovascular Therapy.[a]

Variable	Total (n=31)	Pudendal Artery (n=27)	Penile Artery (n=4)	p
Lesion length, mm	20.6±13.9	23.0±13.3	4.0±1.6	0.008
Reference vessel diameter, mm	2.5±0.7	2.6±0.7	2.0±0.5	0.088
Minimum lumen diameter, mm	0.9±0.6	0.9±0.6	0.7±0.6	0.547
Minimum lumen diameter at baseline, mm	2.0±0.9	2.0±1.0	1.9±0.1	0.758
Minimum lumen diameter at 10 minutes, mm	1.7±1.0	1.6±1.0	1.9±0.1	0.658
Elastic recoil (>10%)	31	27	4	>0.99
Severe elastic recoil (>30%)	14	14	0	0.038
Drug-eluting stent	15	14	1	0.316
Drug-coated balloon	16	13	3	0.316

[a]Continuous data are presented as the mean ± standard deviation; categorical data are given as the number.

Table 3. Overview of Erectile Function in 21 Patients Undergoing Endovascular Revascularization for Erectile Dysfunction Comparing Drug-Eluting Stent (DES) vs Drug-Coated Balloon (DCB).[a]

	Total (n=21)	DES (n=11)	DCB (n=10)	p[b]
IIEF-15				
Baseline	31.3±11.2	30.4±15.6	32.2±12.2	0.726
3 months	49.8±16.8	54.8±15.7	45.2±17.1	0.198
Change over time	18.4±15.8	24.4±13.9	13.0±15.5	0.100
IIEF-15 Question 3[c]				
Baseline	1.0±0.9	1.3±0.9	0.6±0.7	0.078
3 months	3.5±1.5	4.2±1.1	2.9±1.6	0.052
Change over time	2.6±1.4	2.9±1.3	2.3±1.6	0.329
IIEF-15 Question 4[d]				
Baseline	0.8±0.6	0.9±0.6	0.7±0.6	0.525
3 months	2.9±1.7	3.4±1.8	2.5±1.5	0.203
Change over time	2.1±1.5	2.5±1.6	1.7±1.3	0.242

Abbreviation: IIEF, International Index of Erectile Function.
[a]Data are presented as the mean ± standard deviation.
[b]Between the DES and DCB subgroups.
Question 3[c]: When you attempted intercourse, how often were you able to penetrate (enter) your partner?
Question 4[d]: During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

Results

Technical success was obtained in all patients, and no complications related to the primary safety endpoint were encountered. Mean MLD at baseline was 0.9±0.6 mm, which improved to 2.0±0.9 mm immediately after balloon dilation. At 10 minutes after dilation, the MLD was 1.7±1.0 mm. Elastic recoil (lumen compromise >10%) was observed in all 31 lesions and resulted in a mean lumen compromise of 21.1%. Severe recoil (lumen compromise >30%) was observed in 14 arteries, resulting in a 36.3% reduction of the MLD.

DCB angioplasty was performed in 16 lesions using balloon diameters of 2.0, 2.5, 3.0, and 4.0 mm in 6, 4, 5, and 1 lesions, respectively. One flow-limiting dissection after DCB angioplasty was successfully treated with a DES. The 14 lesions with severe recoil were also treated with a DES. Stent diameters were 2, 2.5, 3, and 3.5 mm in 1, 3, 10, and 1 lesions, respectively. During the 3-month follow-up, no TLR or TVR was performed.

Prior to revascularization, the mean baseline IIEF-15 score of the 21 ED patients was 31.3±11.2, which improved to 49.8±16.8 at 3 months after revascularization ($p<0.001$). Accordingly, the scores for Question 3 improved from 1.0±0.9 to 3.5±1.5 ($p<0.002$) and for Question 4 from 0.8±0.6 to 2.9±1.7 ($p<0.001$) within the same interval. Further information on improvements in erectile function is provided in Table 3.

Discussion

The PANPI study[6] was the first trial to describe angiographic characteristics of pelvic arterial obstructions in patients with suspected coronary artery disease and ED unresponsive to PDE-5 inhibitor therapy. In that study, arterial lesions in the internal pudendal artery exhibited atherosclerotic obstructions similar to those in the coronary arteries.

Since ED is mostly of arteriogenic origin, endovascular therapy for erection-related arteries has been recently shown to be feasible and safe.[7,14] Still, the ideal antirestenotic

treatment for ED-related arteries, which are mostly smaller in diameter compared with tibial arteries, remains to be determined.[7]

Within the multicenter, single-arm ZEN trial,[7] zotarolimus-eluting stents were evaluated for the treatment of 45 internal pudendal artery lesions in a total of 30 ED patients. The mean lesion length was 18.0 mm and the mean RVD in the pudendal artery was 2.6 mm. These morphological characteristics are similar to the findings within the present study showing a mean lesion length and RVD of 20.6 mm and 2.5 mm, respectively. The procedural success rate was 100% in the ZEN trial. During follow-up, no stent fractures were observed. However, angiographically verified binary restenosis (⩾50% lumen compromise) was reported to be 34.4% at 6 months and thus much higher when compared with the restenosis rates of the same stent within the coronary circulation.[15]

In the PERFECT-2 study, Wang et al[14] reported outcomes of 22 patients undergoing endovascular therapy of the penile arteries, a more distally located arterial segment of even smaller diameter compared with the internal pudendal tract. In that study, plain balloon angioplasty for isolated penile artery stenosis was analyzed. Technical success was achieved in 91% and the 8-month binary restenosis rate by CTA was 41.2%. In a subsequent trial, the PERFECT-4 study, Wang et al[16] randomized 44 ED patients undergoing angioplasty for penile arteries with an RVD ⩾1.5 mm to plain balloon angioplasty vs additional antirestenotic treatment with paclitaxel-coated balloons. The RVD was 1.8 mm in the plain angioplasty group and 1.9 mm in the group treated with DCBs. At 8 months, binary in-segment restenosis by CTA was 40% in the plain angioplasty group vs 48% in the DCB group.

Given that there were no significant differences in restenosis rates comparing conventional angioplasty with DCB, elastic recoil may be the most important mechanism of failure subsequent to angioplasty of these small-caliber arteries.[9] To prevent elastic recoil, DES are recommended over bare metal stents based on the ZEN trial[7] and our knowledge obtained from tibial artery angioplasty,[9] which has similar morphologies.

The mechanism of elastic recoil hampering endovascular therapy has been reported in coronary[10,17] and tibial arteries.[9] Elastic recoil is a passive but dynamic contraction of the elastic compounds of the arterial wall; it leads to lumen compromise within minutes after balloon angioplasty and is associated with restenosis and an impairment in clinical outcomes. Most coronary arteries are treated with a stent to prevent restenosis from elastic recoil. In erection-related arteries, the incidence of elastic recoil is even higher when compared with tibial arteries.[9] However, not all tibial lesions are treated with a stent. The average tibial lesion length is typically >8 cm,[18] which may serve as an explanation for the higher incidence of elastic recoil in the present study, with its relatively short lesions (mean 20.6 mm). In the present study, all lesions showing severe elastic recoil (>30%) were successfully treated with stents with the hope of maintaining patency over time. With the exception of one lesion with a flow-limiting dissection (treated with a DES), the lesions with mild elastic recoil were successfully treated with DCB angioplasty; interesting, there were no differences in the restenosis rate or clinical outcomes compared to the patients treated with a stent, but the follow-up was very short. This finding may promote the "leave nothing behind" concept in these relatively young men (mean age 58 years) with ED.

The aforementioned ZEN study[7] evaluated an improvement of the IIEF score ⩾4 as a primary feasibility outcome, which was obtained in 59.3% at 6-month follow-up. The corresponding binary restenosis (⩾50% lumen compromise by angiography) rate was 34.4%. Based on these findings, DES of the pudendal arteries is considered safe and beneficial for the majority of ED patients. Nevertheless, the rate of non-responders was rather high (40.7%), which may be attributed to the microangiopathy frequently observed in ED patients[19] and to concomitant comorbidities.

In the PERFECT-4 study,[16] about 80% of patients showed a direct clinical benefit immediately after revascularization. However, at 12 months, only 50% to 60% of treated patients had a sustained erection benefit. Thus, both plain and DCB angioplasty were associated with moderate clinical success at 12 months.

Conclusion

Endovascular therapy for arteriogenic ED is a promising treatment concept and may be associated with a favorable short-term clinical response in a high subset of patients. Elastic recoil subsequent to plain balloon dilation of the pudendal artery is frequent and may contribute to restenosis in longer follow-up. Further studies are warranted to elucidate the ideal antirestenosis concept for these small-diameter arteries.

Declaration of Conflicting Interests

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ORCID iD

Nicolas Diehm https://orcid.org/0000-0001-5674-0073

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